

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appligant:

Bernd DORKEN et al.

Title:

NOVEL CD19xCD3 SPECIFIC POLYPEPTIDES

AND USES THEREOF

Appl. No.:

09/673,735

Filing Date:

December 27, 2000

Examiner:

Unassigned

Art Unit:

Unassigned

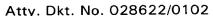
INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents Washington, D.C. 20231

Sir:

Submitted herewith on Form PTO-1449 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.



CONCISE EXPLANATION OF RELEVANCE OF EACH DOCUMENT

Documents A1 - A10 came to Applicants' attention during the prosecution of the corresponding International application. A copy of the International Search Report is attached setting forth the portion of each document considered relevant by the examiner.

Documents A11 - A16 were mentioned in a response, dated May 16, 2000, to a Written Opinion issued by the European Patent Office acting as the IPEA on February 17, 2000, concerning the International application.

English translations of Documents A1 and A12 are not readily available; however, the absence of such translations does not relieve the PTO from its duty to consider the submitted documents (37 CFR §1.98 and MPEP§603). An English language summary is included with Document A12.

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the filing date of the application.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-1449 be returned in accordance with MPEP §609.

Respectfully submitted,

Date 27 Accember 2000

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Form PTO-1449 U.S. DEPARTMENT OF COMMERCE ATTY, DOCKET NO. SERIAL NO. 028622/0102 09/673,735 (MODIFIED) PATENT AND TRADEMARK OFFICE APPLICANT Bernd DORKEN et al. INFORMATION DISCLOSURE CITATION FILING DATE **GROUP ART UNIT** December 27, 2000 Unassigned (Use several sheets if necessary) **U.S. PATENT DOCUMENTS** FILING DATE **DOCUMENT** SUB-**EXAMINER CLASS** DATE -- NAME REF IF **CLASS** INITIAL NUMBER APPROPRIATE FOREIGN PATENT DOCUMENTS TRANSLATION SUB-DOCUMENT COUNTRY **CLASS** REF DATE **CLASS** NUMBER YES NO Х Fed. Republic of Germany A1 195 31 348 2/27/97 0 505 908 9/30/92 Europe A2 **WIPO** 91/09968 7/11/91 A3 95/11922 5/4/95 **WIPO** A4_ **WIPO** 96/36360 11/21/96 A5 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) H. Bohlen et al., "TREATMENT OF EB-VIRUS INDUCED B-CELL LCL IN SCID-HU MICE USING CD3XCD19 A6 BISPECIFIC AND CD28 ANTIBODIES.", Proceedings of the American Association for Cancer Research, vol. 35, March, 1994, pg. 510, XP-002076122, abstract. A7 Jan De Jonge et al., "Bispecific antibody treatment of murine B cell lymphoma.", Cancer Immunology Immunotherapy, vol. 45, No. 3/4, pp. 162-165, XP-002076120, Springer-Verlag, 1997 Sergey M. Kipriyanov et al., "BISPECIFIC CD3 X CD19 DIABODY FOR T-CELL-MEDIATED LYSIS OF MALIGNANT HUMAN B CELLS.", International Journal of Cancer, vol. 77, August 31, 1998, pp. 763-772, XP-**8**A 002115487, Wiley-Liss, Inc., 1998 P. Kufer et al., "Construction and biological activity of a recombinant bispecific single-chain antibody designed for therapy of minimal residual colorectal cancer.", Cancer Immunology Immunotherapy, vol. 45, No. 3/4, pp. Α9 193-197, XP-002076121, Springer-Verlag, 1997 Anja Schroder et al., "A RECOMBINANT BISPECIFIC SINGLE CHAIN ANTIBODY CD19XCD3 INDUCED RAPID B CELL LYMPHOMA-DIRECTED CYTOTOXICITY OF UNSTIMULATED HUMAN T CELLS.", 40th A10 Annual Meeting Of The American Society Of Hematology Miami Beach, Florida, December 4-8, 1998, XP-002115457, abstract. DATE CONSIDERED **EXAMINER** EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include any copy of this form with next communication to applicant.

Page 2 of 2

| Form PTO-1449 | U.S. DEPARTMENT OF COMMERCE | ATTY. DOCKET NO. | SERIAL NO. | |
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| (MODIFIED) | PATENT AND TRADEMARK OFFICE | 028622/0102 | 09/673,735 | |
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| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | |
| A | | "National Cancer Institute Sponsored Study of Classifications of Non-Hodgkin's Lymphomas, Summary and Description of a Working Formulation for Clinical Usage.", Cancer, vol. 49, pp. 2112-2135, 1982, (Exhibit 1) | | |
| A ² | Harald Stein et al., "Die neue WHO-Klass C-2302-C-2309, December, 1999, includi | sifikation der malignen Lymphome.", Deutsches Arzteblatt, vol. 96, pp. ing English language summary, (Exhibit 2) | | |
| A ² | Parveen Kumar et al., 3 rd Edition, Clinica | cal Medicine, pp. 369-370, Bailliere Tindall, (Exhibit 3) | | |
| A | Jan De Jonge et al., "PRODUCTION AND FRAGMENTS.", Molecular Immunology, v | Jan De Jonge et al., "PRODUCTION AND CHARACTERIZATION OF BISPECIFIC SINGLE-CHAIN ANTIBODY FRAGMENTS.", Molecular Immunology, vol. 32, No. 17/18, pp. 1405-1412, 1995, (Exhibit 4) | | |
| A ² | 15 Fv (Anti-CD3 X Anti-Idiotype) Induces Lo | Jan De Jonge et al., "In Vivo Retargeting of T Cell Effector Function by Recombinant Bispecific Single Chain Fv (Anti-CD3 X Anti-Idiotype) Induces Long-Term Survival in the Murine BCL1 Lymphoma Model ¹ .", The Journal of Immunology, vol. 161, pp. 1454-1461, 1998, (Exhibit 5) | | |
| A | | Matthias Mack et al., "Biologic Properties of a Bispecific Single-Chain Antibody Directed Against 17-1A (EpCAM) and CD3.", Proceedings of the National Academy of Science, vol. 92, pp. 7021-7025, 1995, (Exhibit 6) | | |
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